

varied from 19 for warts, to 27 for CIN 3 and approximately 450 for cancer and was similar for the differently aged cohorts. Results were sensitive to the duration of vaccine efficacy and coverage. If vaccine coverage was as low as 30%, the NNV for warts, CIN 3 and cancer would increase to 50, 57 and 1115 respectively. If the duration of efficacy was only 10 years instead of a lifetime, the NNV would increase to 62 for warts, 67 for CIN 3 and over 1100 for cancer. **CONCLUSION:** These analyses suggest that the NNV for warts and cervical pre-cancer using a quadrivalent HPV vaccine is low, but will depend on the duration of vaccine efficacy as well as coverage.

**PCN47**

**EVALUATION OF FACTOR STRUCTURE AND RELIABILITY OF THE FUNCTIONAL ASSESSMENT OF CANCER THERAPY—KIDNEY SYMPTOM INDEX**

Shah S<sup>1</sup>, Gondek K<sup>1</sup>, Cella D<sup>2</sup>, Burk K<sup>1</sup>

<sup>1</sup>Bayer Pharmaceuticals Corporation, West Haven, CT, USA, <sup>2</sup>Evanston Northwestern Health care, Evanston, IL, USA

**OBJECTIVES:** The Functional Assessment of Cancer Therapy—Kidney Symptom Index (FKSI) is a 15-item scale that was developed and validated to assess symptoms and concerns of advanced kidney cancer patients. The aim of this study was to evaluate the factor structure of FKSI for possibly useful sub-scales and assess the reliability of the sub-scales. **METHODS:** Data for this study were obtained from a phase III clinical trial of 903 advanced renal cancer patients. Patients were administered FKSI questionnaire at baseline. Baseline data were analyzed using exploratory factor analysis with oblique rotation (promax) to evaluate the dimensional structure of FKSI. The internal consistency of the subscales and overall scale was assessed using Cronbach's alpha. **RESULTS:** Four factors were identified consisting of 13 of the 15 items of FKSI. The first factor had two items related to pain symptoms; the second factor had two items related to respiratory symptoms; the third factor had five items related to general symptoms of the disease and; the fourth factor had four items related to quality of life. All four factors had good reliability (alphas > 0.70). The internal consistency of the overall 13-item scale was excellent (alpha = 0.83). **CONCLUSION:** A four-factor solution consisting of 13 items could easily be labeled with clinically-meaningful concepts, indicating the possibility of four underlying dimensions of kidney cancer symptomatology: pain, respiratory, general symptoms and quality of life. Findings supported the internal consistency of four sub-scales and overall 13-item scale. Sub-scale scores and the total index are reliable and valid measure that can be used to determine the effect of drug therapies on specific symptoms and concerns of advanced kidney cancer.

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**STANDARD GAMBLE TECHNIQUES FOR THE MEASUREMENT OF TREATMENT RELATED TOXICITY IN ONCOLOGY: APPLICATION TO ADVANCED STAGE PROSTATE CANCER**

Simons WR<sup>1</sup>, Tung PJ<sup>2</sup>, Pan KY<sup>3</sup>

<sup>1</sup>Global Health Economics & Outcomes Research Pty Ltd, Sydney, NSW, Australia, <sup>2</sup>sanofi aventis, Sydney, NSW, Australia, <sup>3</sup>Global Health Economics & Outcomes Research Inc, Summit, NJ, USA

**OBJECTIVES:** To assess Australian men's preferences for health states (HS) specific to advanced stage prostate cancer (APC) including baseline diagnoses of APC, response, no response, disease progression and especially treatment-related toxicities by severity apart from other components of the HS which is methodologically different. **METHODS:** FACT-P QOL data from patients with APC were used to compose HS narratives consisting of physical, social, emotional, functional well-being,

additional concerns domains. Treatment-related mild, moderate, severe and life-threatening toxicities were described separately. 100 Australian men were recruited and interviewed using standard gamble techniques (SG). Baseline diagnoses of APC, response, no response and disease progression using SG as usual with oscillating risks of perfect health (1) and immediate death (0) as anchors OR the HS narrative with 100% certainty. For toxicities, however, the true trade-off is treatment response with an associated risk of toxicity OR no treatment and remain with 100% certainty at baseline APC. This obtains how much chance of response a man needs to be indifferent to the corresponding chance of toxicity by severity. **RESULTS:** SG regression results were 0.506 (p < 0.01) for baseline APC, 0.602 (p < 0.01) for response, 0.502 (p < 0.01) for no response, and 0.318 (p < 0.01) for disease progression. The trade-off between a chance of treatment response with a corresponding chance of mild, moderate, severe, or life-threatening toxicity yielded utility scores of 0.794 (p < 0.01), 0.715 (p < 0.01), 0.466 (p < 0.01), and 0.257 (p < 0.01), respectively. **CONCLUSION:** Men need at least a 21%, 28%, 55% or 74% chance of treatment response to be indifferent to treatment related toxicity depending on severity. These measured values are more appropriate for Quality-adjusted Time Without Symptoms of disease and Toxicity (Q-TWiST) analysis where time without disease progression is rewarded while disease progression with toxicities is penalized by applying a utility weights for disease progression and time with toxicity than the usual arbitrary ones.

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**LINGUISTIC VALIDATION OF THE FACT-HEAD AND NECK IN 8 LANGUAGES FOR INDIA**

Herzberg T<sup>1</sup>, Eremenco S<sup>2</sup>, Arnold B<sup>1</sup>

<sup>1</sup>Evanston Northwestern Health Care, Evanston, IL, USA, <sup>2</sup>Evanston Northwestern Health Care/Northwestern University, Evanston, IL, USA

**OBJECTIVES:** The purpose of this study was to translate and linguistically validate the Functional Assessment of Cancer Therapy—Head and Neck V. 4 (FACT-H&N) for Gujarati, Hindi, Kannada, Malayalam, Marathi, Tamil, Telugu and Urdu translations. **METHODS:** The FACT-H&N was originally developed through patient and expert interviews, and validation studies. The FACT-H&N was translated according to the standard FACIT methodology: 2 forward translations, a reconciled version of the 2 forwards, back-translation to English, 3 independent reviews by bilingual experts, and harmonization across all languages. The study sample included 120 patients from 8 regions of India. Patients diagnosed with any type of head and neck cancer completed the translated FACT-H&N and then participated in cognitive debriefing interviews. Statistical analyses (descriptive statistics and reliability analyses) were performed on the quantitative data, and the participant comments were analyzed qualitatively. **RESULTS:** Most of the languages showed acceptable reliability ranging from 0.69 to 0.87 for the H&N subscale despite the small sample size with the exception of Kannada (0.13) and Tamil (0.56). There were no negative patient comments related to the H&N specific items. However, when item-total correlations were examined, it was found that some items performed poorly across some languages. They included mouth dryness, trouble breathing, and communication with others. Of these, only the item about communication seemed to indicate a cultural issue affecting the item's relevance. Small changes were made to the Telugu translation but not to the other languages. **CONCLUSION:** The FACT-H&N has shown good reliability and linguistic validity with 8 language versions. We consider these translations to be acceptable for use in interna-